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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/779,873

02/18/2004

Cassey K. Lee

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MILES & STOCKBRIDGE PC
1751 PINNACLE DRIVE
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MCLEAN, VA 22102-3833

EXAMINER

REIMERS, ANNETTE R

ART UNIT

PAPER NUMBER

3733

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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3 MONTHS

01/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

NT
Application No.

10/779,873

Applicant(s)

CASEY K. LEE

Examiner

Annette R. Reimers

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-87 is/are pending in the application.
- 4a) Of the above claim(s) 41 and 59-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-40, 42-58 and 77-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>11/2/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 2, 2006 has been entered.

Clarification

Regarding claims 77-87, these claims were originally submitted as new claims with applicant's response to the first office action (see amendment to the non-final office action submitted on March 6, 2006). These claims were rejected as being anticipated by Huang (U.S. Patent Number 6,893,465) in the final office action (see final office action dated June 2, 2006). Claims 77-87 were not added and entered after the final office action.

Claim Objections

Claims 33 and 77 are objected to because of the following informalities. It appears that applicant is claiming two central cavities. In claims 33 and 77, lines 3-4, applicant claims a polymer core comprising an annulus surrounding a central cavity and then in lines 4-5, applicant claims said annulus having upper and lower side surfaces and a central cavity. For examination purposes, one central cavity will be considered as

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being part of the polymer core and being surrounded by the annulus. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 33-35, 38-39, 43-44, 46, 57-58, 77-79 and 82-83 are rejected under 35 U.S.C. 102(b) as being anticipated by Stubstad et al. (U.S. Patent Number 3,867,728), cited by applicant.

Stubstad et al. disclose various embodiments of a total prosthesis for replacing the entire human intervertebral disk with a polymer core, e.g. 15, comprising an annulus, e.g. 14, surrounding a central cavity, e.g. 27 the annulus having upper and lower and side surfaces and the central cavity extending completely axially therethrough (see figures 2 and 3), wherein the annulus is made of a first biocompatible material and is shaped and sized to approximate the annulus fibrosus of a natural intervertebral disk, the first biocompatible material being an elastomer having a elastic modulus approximating that of the annulus fibrosus of the natural human intervertebral disk (see

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column 2, lines 40-67 and column 3, lines 1-5), upper and lower transitional plates, e.g. 18, affixed respectively to the upper and lower surfaces of the annulus, the upper and lower transitional plates being made of a second biocompatible polymer material having a durometer hardness greater than that of the first biocompatible polymer (see column 7, lines 65-67 and column 8, lines 1-2), and upper and lower endplates, e.g. 19 (see column 5, lines 52-53), adapted to contact adjacent vertebrae and affixed respectively to the upper and lower transitional plates (see figure 1 and column 3, lines 66-67, and column 4, lines 1-67).

Each of the endplates has an inner surface shaped to contact the outer surface of the transitional plate (see figures 1 and 2). Furthermore, each of the transition plates is molded to the upper and lower surfaces of the annulus (see figures 1 and 2). The cavity is filled with an incompressible liquid (see figure 6). An outer surface of at least one of the endplates is provided with a surface texture, e.g. 20 and 21, adapted for bone ingrowth and at least one of the endplates is provided with a fin, e.g. 22, upstanding from the outer surface and extending away from the anterior edge along a lateral midline of the outer surface (see figure 2).

With regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Stubstad et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read

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on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claims 33-35, 38-39, 42, 46, 47, 50, 52, 57-58, 77-79, 82-83 and 85-87 are rejected under 35 U.S.C. 102(e) as being anticipated by Ross et al. (U.S. Patent Number 6,726,720), previously cited by examiner.

Ross et al. disclose various embodiments of a total prosthesis for replacing the entire human intervertebral disk with a polymer core, e.g. 12, comprising an annulus, e.g. 20, surrounding a central cavity, (see figures 3A-3B) the annulus having upper and lower and side surfaces and the central cavity extending completely axially therethrough (see figures 3A-3B), wherein the annulus is made of a first biocompatible material and is shaped and sized to approximate the annulus fibrosus of a natural intervertebral disk, the first biocompatible material being an elastomer having a elastic modulus approximating that of the annulus fibrosus of the natural human intervertebral disk (see column 4, lines 37-50), domed upper and lower transitional plates, e.g. 22 and 24, affixed respectively to the upper and lower surfaces of the annulus, the upper and lower transitional plates being made of a second biocompatible polymer material having a durometer hardness greater than that of the first biocompatible polymer (see column 6, lines 26-36) and domed upper and lower endplates, e.g. 14 and 16, adapted to contact adjacent vertebrae and affixed respectively to the upper and lower transitional plates (see figure 3A)

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Each of the endplates has an inner surface shaped to contact the outer surface of the transitional plate and each of the endplates has a projection, e.g. 30a or 40, at a posterior edge shaped to form a groove for receiving a posterior edge of a of transition plate (see alternate embodiments of figures 3A-3B and 6). Furthermore, each of the transition plates is molded to the upper and lower surfaces of the annulus (see column 5, lines 8-15). An outer surface of at least one of the endplates is provided with a surface texture, e.g. 14a and 16a, adapted for bone ingrowth and at least one of the endplates is provided with a fin, e.g. 32, upstanding from the outer surface and extending away from the anterior edge along a lateral midline of the outer surface (see figure 3A).

With regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Ross et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36-37, 40, 45, 48, 49, 80-81 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stubstad et al. (U.S. Patent Number 3,867,728), cited by applicant.

Stubstad et al. disclose the claimed invention except for first and second elastomeric synthetic polymer having a durometer hardness in a range of about Shore A70 to about Shore A90 and Shore A100 to about Shore D65, respectively, a first elastomeric synthetic polymer having an e-value in a range of about 3-16 megapascals, a cavity having an e-value of about 1-4 megapascals, and transition plates have thickness dimension at anterior and posterior edges of about 4-7 mm and 1-3 mm, respectively. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Stubstad et al. with all of these features, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 36-37, 40, 45, 48, 49, 53-56, 80-81 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ross et al. (U.S. Patent Number 6,726,720), previously cited by examiner.

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Ross et al. disclose the claimed invention except for first and second elastomeric synthetic polymer having a durometer hardness in a range of about Shore A70 to about Shore A90 and Shore A100 to about Shore D65, respectively, a first elastomeric synthetic polymer having an e-value in a range of about 3-16 megapascals, a cavity having an e-value of about 1-4 megapascals, transition plates have thickness dimension at anterior and posterior edges of about 4-7 mm and 1-3 mm, respectively, the upper and lower endplates having a maximum depth of curvature of about 1.5-2.5 mm and 0.6-2.0 mm , respectively, and the maximum depth of curvature being located at a point spaced from an anterior edge of the endplate by a distance of about 60% of an antero-posterior diameter of the endplate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Ross et al. with all of these features, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments with respect to claims 33-40, 42-58, 77-87 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

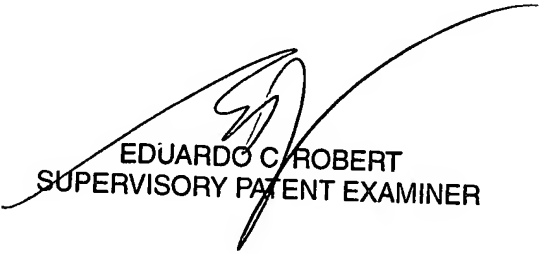
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER